IN THE UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF TEXAS
DALLAS DIVISION

RICKEY L. HOLLAND, ET AL.	§	
	§	
Plaintiffs,	§	
	§	
VS.	§	NO. 3-06-CV-1298-BD
	§	
HOFFMAN-LA ROCHE, INC.	§	
	§	
Defendant.	§	

MEMORANDUM ORDER

Defendant Hoffman-La Roche, Inc. has filed a motion for summary judgment and a motion for partial summary judgment in this products liability case involving the prescription drug CellCept. The gravamen of plaintiff's complaint is that defendant failed to adequately warn physicians and consumers that myasthenia gravis patients have an increased risk of developing cytomegalovirus infection, or CMV, with the use of CellCept in doses exceeding 2.0 grams per day, which makes the product inherently unsafe and unreasonably dangerous. Plaintiff also asserts claims for negligence per se and breach of warranty. In two motions, defendant seeks summary judgment as to all claims and causes of action. Plaintiff was ordered to file a response to the motions by September 6, 2007, but has failed to do so. The court therefore considers the summary judgment motions without the benefit of a response.

Summary judgment is proper when there is no genuine issue as to any material fact and the movant is entitled to judgment as a matter of law. FED. R. CIV. P. 56(c). A party seeking summary judgment bears the initial burden of showing the absence of a genuine issue for trial. *See Duffy v. Leading Edge Products, Inc.*, 44 F.3d 308, 312 (5th Cir. 1995). This may be done by "pointing out

'the absence of evidence supporting the nonmoving party's case.'" *Id., quoting Skotak v. Tenneco Resins, Inc.*, 953 F.2d 909, 913 (5th Cir.), *cert. denied*, 113 S.Ct. 98 (1992). Once the movant meets this burden, the nonmovant who has the burden of proof at trial must show that summary judgment is not proper. *See Duckett v. City of Cedar Park*, 950 F.2d 272, 276 (5th Cir. 1992). Where, as here, the non-movant has not filed a summary judgment response or submitted any controverting evidence, the court may accept as true the undisputed facts adduced by the movant. *See Tillison v. Trinity Valley Electric Cooperative, Inc.*, No. 3-03-CV-2480-D, 2005 WL 292423 at *1 (N.D. Tex. Feb. 7, 2005), *citing Bookman v. Shubzda*, 945 F.Supp. 999, 1002 (N.D. Tex.1996). All evidence must be viewed in the light most favorable to the party opposing the motion. *Rosado v. Deters*, 5 F.3d 119, 122 (5th Cir.1993).

Plaintiff Rickey Holland is a 53 year-old male who suffers from generalized myasthenia gravis, a chronic disease in which the body's immune system mistakenly attacks receptors involved in transmitting nerve impulses to muscles. (*See* Def. MSJ App. at 005, 008-009, ¶ 5 & 017, ¶ 9). In order to control the symptoms of plaintiff's disease, his neurologist recommended a daily 3.0 gram dose of CellCept, a drug manufactured by defendant. (*Id.* at 080, 085, 094-095, 106). Plaintiff used the drug in the prescribed dosage from August 2000 until December 2003, when he contracted an infection that progressed to septic shock. (*Id.* at 113). Ultimately, plaintiff was diagnosed with CMV. (*Id.* at 011, ¶ 18 & 113). Following his recovery, plaintiff resumed taking CellCept at a lower dosage of 1.5 to 2.0 grams per day. (*Id.* at 114).

CellCept, whose generic name is mycophenolate mofetil, is an immunosuppressant approved by the Food and Drug Administration ("FDA") to prevent organ rejection in transplant patients. (*Id.* at 018, ¶ 12). The drug is also sometimes used to treat patients who, like plaintiff, suffer from

myasthenia gravis.[1] Like all prescription medications, CellCept has potential adverse side effects, some of which may be severe. Among the known side effects of the drug are an increased susceptibility to infection. (*Id.* at 011, ¶ 17). As required by FDA regulations, defendant developed package labeling and a product description for CellCept.[2] The first item on the CellCept label is a "black box" warning – the strongest warning contemplated by FDA regulations – that states:

> **Increased susceptibility to infection and the possible development of lymphoma may result from immunosuppression. Only physicians experienced in immunosuppressive therapy and management of renal, cardiac or hepatic transplant patients should use CellCept. Patients receiving the drug should be managed in facilities equipped and staffed with adequate laboratory and supportive medical resources. The physician responsible for maintenance therapy should have complete information requisite for the follow-up of the patient.**

(*Id.* at 045). The label further advises:

> **WARNINGS (see boxed WARNING):** Patients receiving immunosuppressive regimens involving combinations of drugs, including CellCept, as part of an immunosuppressive regimen are at increased risk of developing lymphomas and other malignancies, particularly of the skin (see ADVERSE REACTIONS). The risk appears to be related to the intensity and duration of immunosuppression rather than to the use of any specific agent. Oversuppression of the immune system can also increase susceptibility to infection, including opportunistic infections, fatal infections, and sepsis.

(*Id.* at 058). The label also includes information about various adverse events:

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[1] The use of CellCept to treat myasthenia gravis is considered an "off-label" use. (*See* Def. MSJ App. at 010, ¶ 11 & 018, ¶ 11).

[2] The FDA requires a prescription drug label to contain "a summary of the essential scientific information needed for the safe and effective use of the drug." 21 C.F.R. § 201.56(a)(1). The labeling must be "informative and accurate and neither promotional in tone nor false or misleading in any particular." *Id.* § 201.56(a)(2). Specific labeling requirements are found at 21 C.F.R. § 201.57.

> **ADVERSE REACTIONS:** The principal adverse reactions associated with the administration of CellCept include diarrhea, leukopenia, sepsis, vomiting, and there is evidence of a higher frequency of certain types of infections, eg, opportunistic infection (see WARNINGS).

(*Id.* at 065). Finally, the CellCept label warns doctors that "[i]n patients receiving CellCept (2g or 3g) in controlled studies for prevention of renal, cardiac or hepatic rejection, fatal infection/sepsis occurred in approximately 2% of renal and cardiac patients and in 5% of hepatic patients." (*Id.* at 069).

One of the grounds urged by defendant in its motion for summary judgment is that plaintiff cannot prevail on his failure-to-warn claim in light of the FDA-approved warnings. Under Texas law, which applies in this diversity case, there is a rebuttable presumption that the manufacturer of a pharmaceutical product is "not liable with respect to [ ] allegations involving failure to provide adequate warnings or information if . . . the warnings or information that accompanied the product in its distribution were those approved by the [FDA]." *See* TEX. CIV. PRAC. & REM. CODE ANN. § 82.007(a)(1) (Vernon 2005). A plaintiff may rebut the presumption by establishing one of the following exceptions:

> (1) the defendant, before or after pre-market approval or licensing of the product, withheld from or misrepresented to the United States Food and Drug Administration required information that was material and relevant to the performance of the product and was causally related to the claimant's injury;
>
> (2) the pharmaceutical product was sold or prescribed in the United States by the defendant after the effective date of an order of the United States Food and Drug Administration to remove the product from the market or to withdraw its approval of the product;
>
> (3)(A) the defendant recommended, promoted, or advertised the pharmaceutical product for an indication not approved by the United States Food and Drug Administration;

(B) the product was used as recommended, promoted, or advertised; and

(C) the claimant's injury was causally related to the recommended, promoted, or advertised use of the product;

(4)(A) the defendant prescribed the pharmaceutical product for an indication not approved by the United States Food and Drug Administration;

(B) the product was used as prescribed; and

(C) the claimant's injury was causally related to the prescribed use of the product; or

(5) the defendant, before or after pre-market approval or licensing of the product, engaged in conduct that would constitute a violation of 18 U.S.C. Section 201 and that conduct caused the warnings or instructions approved for the product by the United States Food and Drug Administration to be inadequate.

Id. § 82.007(b). Here, plaintiff presents no evidence to rebut the presumption that the FDA-approved warnings and information for CellCept, including the risk of susceptibility to opportunistic infection and sepsis that increases with prolonged use of the drug in higher doses, were adequate. Although plaintiff's doctor prescribed CellCept for an "off label" use, there is no suggestion that defendant "recommended, promoted, or advertised the pharmaceutical product for an indication not approved by the [FDA]." *Id.* § 82.007(b)(3)(A). Defendant is therefore entitled to summary judgment with respect to plaintiff's failure-to-warn claim.

Nor is there a triable issue with respect to plaintiff's other claims. Prescription drugs are not susceptible to a design defect claim where, as here, the drug is "accompanied by proper directions and warning." *Hackett v. G.D. Searle & Co.*, 246 F.Supp.2d 591, 595 (W.D. Tex. 2002), *citing*

Restatement (Second) Torts § 402A, comment k.[3] Texas courts also refuse to recognize a cause of action for negligence per se based on violations of the Food and Drug Cosmetic Act ("FDCA") and FDA regulations. *Id.* at 594; *see also Talley v. Danek Medical, Inc.*, 179 F.3d 154, 161 (4th Cir. 1999) (refusing to allow plaintiff to enforce the FDCA through state law negligence per se action). Finally, plaintiff never gave defendant notice of his breach of warranty claim before filing suit as required by Texas law. *See Martin v. Home Depot U.S.A. Inc.*, 369 F.Supp.2d 887, 893 (W.D. Tex. 2005), *citing* Tex. Bus. & Comm. Code. Ann. § 2.607(c)(1) (Vernon 1994) (buyer must notify seller within a "reasonable time" after he discovers breach of warranty or be barred from any remedy); *U.S. Tire-Tech, Inc. v. Boeran, B.V.*, 110 S.W.3d 194, 199 (Tex. App.--Houston [1st Dist.] 2003, pet. denied) (pre-suit notice requirement is condition precedent to cause of action for breach of warranty).

CONCLUSION

For these reasons, defendant's motion for summary judgment [Doc. #13] and defendant's motion for partial summary judgment [Doc. #20] are granted. The court will dismiss this case with prejudice by separate judgment filed today.

SO ORDERED.

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[3] Comment k states:

> There are some products which, in the present state of human knowledge, are quite incapable of being made safe for their intended and ordinary use. These are especially common in the field of drugs. . . . *Such a product, properly prepared, and accompanied by proper directions and warning, is not defective, nor is it unreasonably dangerous.* . . . The seller of such products, again with the qualification that they are properly prepared and marketed, and proper warning is given, where the situation calls for it, is not to be held to strict liability for unfortunate consequences attending their use, merely because he has undertaken to supply the public with an apparently useful and desirable product, attended with a known but apparently reasonable risk.

Rest. (2d) Torts, § 402, cmt. k (emphasis added).

DATED: November 15, 2007.

JEFF KAPLAN
UNITED STATES MAGISTRATE JUDGE